

Appln No. 10/561.631
Amdt date June 16, 2010
Reply to Office action of March 3, 2010

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Withdrawn and Currently Amended) A process for the preparation of isotonic oil emulsions ~~containing estrogen and progestagen~~ for intravenous administration, comprising the steps of:

- (A) providing at least one of estrogens and progestagens;
providing an oil phase and an aqueous phase;
providing an antioxidant;
dissolving ~~the~~ at least one of ~~the hormones~~ estrogen and progestagen in ~~in~~ [[an]]the
oil phase; and
- (B) emulsifying the oil phase in the aqueous phase; in the presence of an emulsifier.

2. (Currently Amended) A hormone-containing isotonic oil emulsion for intravenous administration comprising:

- at least one of progestagens and estrogens~~[[,]]~~;
- an oil phase;
- an antioxidant;
- an emulsifier; and
- an aqueous phase;
wherein the at least one of the progestagens and estrogens are dissolved in the oil
phase prior to being mixed with the aqueous phase ~~obtainable by the process according to~~
~~claim 1.~~

3. (Original) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2, comprising progestagens and estrogens in a ratio of from

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2:1 to 200:1.

4. (Currently Amended) The oil emulsion according to claim 2 ~~or 3~~, characterized in that the emulsion contains from ~~[[1]]0.005~~ to ~~[[60]]0.5~~% by weight of an estrogen and from ~~[[1]]0.05~~ to ~~[[50]]5~~% by weight of a progestagen, based on the total composition.

5. (Currently Amended) The oil emulsion according to ~~any of claim~~[[s]] 2 ~~to 4~~, characterized in that said estrogen is estradiol and said progestagen is progesterone.

6. (Currently Amended) The oil emulsion according to ~~any of claim~~[[s]] 2 ~~to 5~~, characterized in that said oil phase comprises medium chain triglycerides (MCT) having a chain length of from 6 to 12, preferably from 8 to 10, carbon atoms.

7. (Currently Amended) The oil emulsion according to ~~any of claim~~[[s]] 2 ~~to 6~~, characterized by containing up to 1.5% by weight of the emulsifier, based on the total composition.

8. (Withdrawn) Use of the isotonic oil emulsion according to any of claims 2 to 7 for preparing a medicament for intravenous administration of estrogen and progestagen for postnatal hormone substitution in premature babies.

9. (Withdrawn) Use of the isotonic oil emulsion according to any of claims 2 to 7 for preparing a medicament for the treatment of neurological damage after strokes.

10. (Withdrawn) A process for hormone substitution in premature babies by using the isotonic oil emulsion according to any of claims 2 to 7.

11. (Withdrawn) A process for the treatment of neurological damage after strokes by

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using the isotonic oil emulsion according to any of claims 2 to 7.

12. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; further comprising a co-emulsifier.

13. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 12, wherein the co-emulsifier is present in an amount of from 0.005 to 0.1% by weight, based on the total composition.

14. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; wherein the antioxidant comprises tocopherols or tocopherol esters.

15. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; wherein the antioxidant is present in an amount from about 10mg to 1000mg, based on 100g of the oil phase.

16. (New) The hormone-containing isotonic oil emulsion for intravenous administration according to claim 2; having a pH value from 6.0 to 9.0.